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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/684,026	10/06/2000	Anthony Louis Devico	11076-002001	3193

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EXAMINER
WINKLER, ULRIKE

ART UNIT	PAPER NUMBER
1648	12

DATE MAILED: 04/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/684,026	Applicant(s) DEVICO ET AL.	
	Examiner Ulrike Winkler, Ph.D.	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 March 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-72* is/are pending in the application.

4a) Of the above claim(s) *18-23 and 25-72* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5 and 7* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Applicant's election with traverse of Group I in Paper No. 11 is acknowledged. The traversal is on the ground(s) that the groups fall in the same class and thereby would not be a burden to search. This is not found persuasive because, although the group may be in the same class, they differ in their subclasses. Furthermore, the claims are drawn to a structure, adding additional components to the base structure changes the whole molecule and requires further consideration. To illustrate the conceptual structural differences a figure is attached to the instant office action in order to illustrate that the claimed inventions are structurally very different, additionally two references are added in order to illustrate that minor molecular rearrangements can have profound effect on the immunogenicity of a compound providing further evidence that each structure requires different considerations (Patidos et al., European Journal of Immunology 1992 and Zeng et al. Vaccine 2001). Therefore, in regard to the groups not being a burden to examine, the state of the art is such that it recognizes the differences in these groups. Because the fields of search must be pertinent to the subject matter covered by the claims the search for one group will not be coextensive for the other group resulting in a serious burden to the examiner to evaluate all groups.

The requirement is still deemed proper and is therefore made FINAL.

Sequence listing

Applicant's CRF and paper sequence listing have been entered.

Information Disclosure Statement

An initialed and dated copy of Applicant's IDS form 1449, Paper No. 5 and 7, is attached to the instant Office Action.

Drawings

The drawings are objected to, please see Notice of Draftsperson's Review attached to the instant Office Action. Correction is required.

Applicant is reminded of the new changes to the drawing requirements attached to Notice of Draftsperson's Review. Applicant is required to submit the drawing corrections within the time period of response set in the instant office action (see 37 CFR 1.85(a)).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 1, it is not clear what is meant by "bind each other" in the phrase "...wherein the coat polypeptide sequence and the viral receptor polypeptide sequence bind each other". In the context of the claim, does "bind each other" refer to the chimera where A and B are fused by a peptide bond and thereby "bind each other" or does "bind each other" refer to the coat protein and viral receptor that would bind each other in a natural

infection? The claims are rejected because of this uncertainty of the meaning of "bind each other".

Claims 1-17, and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear what applicant intends by a "chimeric polypeptide" because in the claims (claim 1 specifically) the "chimeric polypeptide" is linked by a spacer, which takes the chimeric polypeptide out of the realm of simply being a fusion protein. One of ordinary skill in the art would normally interpret a chimera to be a fusion portion made up of two heterologous sequences. It is apparent from applicants claims and the specification that applicant intends a "chimeric polypeptide" to be any combination of two proteins that are linked by any means. Therefore, it is not clear what applicant intends to exclude or include in their use of the term "chimeric polypeptide".

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a chimera between CD4 and gp120, does not reasonably provide enablement for a chimera utilizing a peptide mimetic spacer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. In order to make a

mimetic there is a requirement for the knowledge of the three dimensional structure of the molecules that are indented to be emulated (Moore G.J. Designing peptide mimetics, Trends in Protein Science. Vol. 15 (1994) pages 124-129). A peptide mimetic is a molecule that mimics the biological activity of a peptide but is no loner peptidic in chemical structure. The term mimetic is sometimes used to describe molecules that are no longer completely peptidic in nature, such as pseudopeptides and peptoids, but a strict definition is a molecule that no longer contains any peptide bonds and has a molecular weight of less than 700 daltons. To make a peptide mimetic there needs to be sufficient knowledge about the structure-activity relationships of a given peptide in order to identify the crucial pharmacophoric groups. This is usually achieved by NMR spectroscopy or X-ray diffraction studies which are used to construct a model. Presently available software is not sufficiently sophisticated to generate a biologically active conformation, but are useful for optimizing distances. The last stage in a mimetic design requires the construction of a template from which active pharmacophoric groups are mounted. This is the most unpredictable step and requires the artisan's intuition and therefore makes the construction and design of a mimetic unpredictable.

The specification does not provide the requisite information in order to reliably produce a peptide mimetic spacer that would functionally link the two molecules while retaining their desired activity. Therefore, the instant invention is not enabled for the full scope of the claimed invention contemplated.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Chackerian et al. (Proceeding of the National Academy of Sciences, March 1999).

The instant invention is directed to a chimeric polypeptide comprising a viral coat polypeptide sequence and a viral receptor. The sequences are linked by a spacer which includes one or more amino acids, a peptidomimetic, a carbohydrate spacer, and other moieties that can function to allow formation of an interacting complex between the virus coat polypeptide sequence and receptor polypeptide sequence (specification, page 14, line 23-31). The definition of a spacer would include a chemical cross-linker or a peptide bond. Because it is not clear what is meant by "bind each other" (see 35 U.S.C. 112, second paragraph above) for the instant claims "bind each other" is interpreted to be "fused to each other via a peptide bond".

Chackerian et al. disclose chimeric L1-CCR5 proteins, L1 is the viral capsid protein from bovine papillomavirus type-1 and CCR5 is a cell surface receptor and a coreceptor for HIV. The chimera comprises viral coat sequences and viral receptor sequences. Therefore, the instant invention is anticipated by Chackerian et al.

Claims 1-8, 10, 11 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by DeVico et al. (U.S. Pat. No. 5,518,723, IDS) or DeVico et al. (U.S. Pat. No. 5,843,454, IDS).

The instant invention is directed to a chimeric polypeptide comprising a viral coat polypeptide sequence and a viral receptor. The sequences are linked by a spacer which includes one or more amino acids, a peptidomimetic, a carbohydrate spacer, and other moieties that can function to allow formation of an interacting complex between the virus coat polypeptide sequence and receptor polypeptide sequence (specification, page 14, line 23-31). The definition of a spacer would include a chemical cross-linker or a peptide bond.

DeVico et al. disclose in both patents CD4-gp120 complexes that have been covalently linked using a reactive spacer molecule. The reference teaches using the complex as a vaccine. Therefore, the instant invention is anticipated by DeVico et al.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8, 10, 11 and 24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3 of U.S. Patent No. 5,518,723. Although the conflicting claims are not identical, they are not patentably distinct

from each other because the instant invention is directed to a chimeric polypeptide comprising a viral coat polypeptide sequence and a viral receptor. The sequences are linked by a spacer, which includes one or more amino acids, a peptidomimetic, a carbohydrate spacer, and other moieties that can function to allow formation of an interacting complex between the virus coat polypeptide sequence and receptor polypeptide sequence (specification, page 14, line 23-31). The definition of a spacer would include a chemical cross-linker or a peptide bond. The U.S. Patent No. 5,518,723 disclose CD4-gp120 complexes that have been covalently linked using a reactive spacer molecule. The patent includes the complex in a pharmaceutically acceptable carrier.

Claims 1-8, 10, 11 and 24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,843,454. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant invention is directed to a chimeric polypeptide comprising a viral coat polypeptide sequence and a viral receptor. The sequences are linked by a spacer which includes one or more amino acids, a peptidomimetic, a carbohydrate spacer, and other moieties that can function to allow formation of an interacting complex between the virus coat polypeptide sequence and receptor polypeptide sequence (specification, page 14, line 23-31). The definition of a spacer would include a chemical cross-linker or a peptide bond. The U.S. Patent No. 5,843,454 disclose CD4-gp120 complexes that have been covalently linked using a reactive spacer molecule in a pharmaceutically acceptable carrier.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ulrike Winkler, Ph.D.

JEFFREY STUCKER
PRIMARY EXAMINER